# VAN HOVEN DECL.
# ISO OPPOSITION TO INTUITIVE'S MOTION TO REOPEN DISCOVERY

# EXHIBIT 5

Intuitive
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January 29, 2020

Dr. William Maisel
Director, Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration
Building W066, Room 1678
10903 New Hampshire Avenue
Silver Sprint, MD 20993-0002

Dear Dr. Maisel:

We are writing to bring to your attention a public safety concern arising from certain remanufacturing activities that a number of companies are performing on robotic instruments originally manufactured by Intuitive Surgical ("Intuitive"). As discussed more fully below, these companies are modifying Intuitive's robotic instruments in order to extend their use beyond the number of uses for which they have been validated. Intuitive is concerned that the companies' activities, which do not appear to comply with the applicable device manufacturer requirements in the Federal Food, Drug, and Cosmetic Act ("FDCA"), have the potential to negatively impact the safety and performance of the robotic instruments, thus posing a risk to patients. We are also concerned that hospitals are purchasing and using these remanufactured devices on patients based on an incorrect understanding – asserted by the companies remanufacturing the devices – that the remanufacturing of robotic instruments is not subject to FDA regulation. We respectfully request that FDA promptly investigate these activities and take any appropriate actions. We also respectfully request the opportunity to meet with you to further discuss these issues.

***Intuitive's Reposable EndoWrist Instruments***

Intuitive designs, manufactures and sells da Vinci surgical systems as well as instruments and accessories for use with the da Vinci system. Both the da Vinci system and the Intuitive instruments and accessories are regulated as Class II devices that have been cleared by FDA via 510(k). Many of Intuitive's instruments, known commercially as EndoWrist Instruments, are reposable devices that have been validated for a specified number of uses and are labeled as such. Examples include needle drivers, graspers, and electrocautery instruments such as scissors, forceps and permanent cautery hooks.

INTUITIVE.

The validation is critical to patient safety because the instruments gradually degrade both from use in surgery and repeated cleaning and sterilization cycles required between uses. Consistent with FDA's 2015 guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" (the "2015 Guidance"), and to ensure the safe use of reposable EndoWrist Instruments in conformity with the device labeling, EndoWrist Instruments are equipped with a chip that tracks the number of remaining uses and disables the instrument for use with the da Vinci at the end of its useful validated life as identified on the product labeling (the "Life-Tracking Chip").[1]

***Unlawful Remanufacturing of EndoWrist Instruments***

We are aware that at least the following companies appear to be engaging in the unlawful remanufacturing of EndoWrist Instruments: Restore Robotics (https://www.restorerobotics.com/) and Rebotix Repair (https://rebotixrepair.com/) (collectively, the "EndoWrist Remanufacturers"). We note that the companies performing these activities are clearly "Remanufacturers," as that term is defined in FDA's regulations. Specifically, "Remanufacturer" means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use. 21 C.F.R. 820.3(w). EndoWrist Instruments are intended and labeled to be used for a specified number of times as determined through reliability testing (e.g., 10 uses). These original performance specifications were validated through comprehensive testing regarding packaging, shelf life, biocompatibility, software, electrosurgical performance, electromagnetic compatibility, electrical safety, mechanical and electrical performance, reliability, and human factors. Intuitive submitted this validation testing information to FDA as part of the 510(k) process for the EndoWrist Instruments. The EndoWrist Remanufacturers significantly change the original performance and safety specifications of the EndoWrist Instruments by "resetting" the Life-Tracking Chip to allow the device to be reused more times than are specified in Intuitive's labeling, and necessitating that the device be re-sterilized more times than its validation testing supports.

One of these entities, Restore Robotics ("Restore"), touts itself on its website and in its written promotional materials as "the world's first provider of a repair/reset

[1] The 2015 Guidance provides, in pertinent part: "Reuse life may also be addressed by validating the number of times the product can be reprocessed and reused, and providing this specification in the labeling. If the reuse life of a device is limited to a specific number of use/reprocessing cycles, the labeling should also describe a specific tracking method for the number of reuse cycles" (emphasis added).

service for da Vinci S and Si surgical instruments." Restore instructs hospitals who purchase and use EndoWrist Instruments in their practice to send Intuitive EndoWrist Instruments to Restore that "have only 1 use left" based on the instrument's Life-Tracking Chip. According to the company's website, "Restore Robotics will utilize [its] proprietary and patented process to restore the available uses to [the instrument's] original state."

Through our complaint process, we have received EndoWrist Instruments that were placed back on the market after having been modified by the EndoWrist Remanufacturers, and thus we have been able to determine that the EndoWrist Remanufacturers' process includes breaking into the instruments and altering the devices from their original condition in a manner that could harm certain components and cause danger to the patient. This includes the EndoWrist Remanufacturers accessing the EndoWrist Instruments' inner components by forcibly removing the permanent housing covering a portion of the instruments and adding additional components not in the original device.

The EndoWrist Remanufacturers electrically connect a newly-installed third-party circuit board, which circumvents the original Life-Tracking Chip. The EndoWrist Remanufacturers then leverage these modifications to add lives to the devices beyond the number validated by Intuitive and specified in the devices' labeling. The devices returned to the customer appear identical to the original EndoWrist Instruments; however, as a result of the modification and reprogramming conducted by the EndoWrist Remanufacturers, and despite the fact that the devices appear to be original EndoWrist Instruments, the devices are substantially different. Restore claims that EndoWrist Instruments may be "reset" up to 6-8 times, thus potentially facilitating 60-80 reuses of the device beyond the number of reuses validated by Intuitive and reflected in the device's labeling.

As remanufacturers, these companies are subject to the full range of device manufacturer requirements, including, among other things, obtaining clearance of a 510(k) submission, and complying with Quality System Regulation, MDR Reporting, Reports of Corrections and Removals, and Establishment Registration and Device Listing requirements. Based on our research, however, none of the EndoWrist Remanufacturers appears to comply with any of these requirements. Indeed, to our knowledge, FDA has not had an opportunity to review any of the EndoWrist Remanufacturers' new specifications, testing methods, or results, because these companies have not submitted 510(k)s to FDA for their remanufactured devices.

At least one company is mischaracterizing its activities in order to position itself as not subject to the regulatory obligations applicable to remanufacturers. Restore claims in its marketing materials that their "service violates none of the standards that could necessitate a 510K [sic], " because, *inter alia*,

- "There are no changes to the performance or safety specifications of the instrument" and
- The devices [sic] intended use is not significantly altered. The EndoWrist's 510K [sic] and IFU denote the instrument as a reusable device and they remain so." See Attachment A.

These claims are not supported by the facts. As noted above, the EndoWrist Remanufacturers significantly alter the performance/safety specifications of the EndoWrist Instruments by facilitating their reuse well beyond their useful life as indicated in the products' labeling. These activities go far beyond mere "repair" of the devices and instead constitute remanufacturing of a new, unapproved medical device, for which the EndoWrist Remanufacturers hold full FDA regulatory responsibility. In this regard, we note that the EndoWrist Remanufacturers have not labeled their remanufactured devices such that customers understand that complaints regarding the devices should be directed to the EndoWrist Remanufacturers, who are responsible for evaluating them for MDR reportability and submitting required MDRs to FDA. Instead, Intuitive receives complaints on the EndoWrist Remanufacturers' remanufactured devices, which creates confusion with regard to the monitoring of postmarket safety signals.

***Potential Risk to Patient Safety***

The unlawful remanufacturing activities described above pose a potentially significant risk to patient safety. Intuitive's EndoWrist Instruments are designed and tested to achieve a targeted level of safety, precision, and dexterity over the programmed number of instrument uses. Gradual degradation of the instrument occurs both from use in surgery as well as repeated cleaning and sterilization cycles required between uses. Examples of degraded performance may include, but are not limited to:

- Unintuitive motion (i.e., instruments do not track well with master manipulators; unexpected motion or stalls);
- Insufficient grip force;
- Dull or damaged scissor blades; and
- Worn/damaged cables.

With continued use beyond the instruments' determined useful life, the wear and tear from these additional uses may reduce the instruments' safety, precision, and dexterity. EndoWrist Remanufacturers also may be using non-validated or incompatible cleaning agents and/or disinfection/sterilization processes, which have the potential to damage the instruments, thereby negatively affecting product performance and creating potential risk for patients. In addition, by reprogramming the EndoWrist Instruments to add lives beyond the number validated by Intuitive and specified in the device's labeling, the EndoWrist Manufacturers are disrupting the traceability of these devices, which could make it difficult to identify all affected instruments in a recall situation.

Intuitive has seen firsthand examples of some of the problems described above. For instance, remanufactured EndoWrist scissors have been returned to Intuitive with dull blades in conjunction with feedback from the customer that the device did not cut properly.

***Judicial Decisions Enjoining EndoWrist Remanufacturers' Activities***

Finally, we note that the EndoWrist Remanufacturers are providing unlawfully remanufactured EndoWrist Instruments to hospitals both within and outside of the US – and courts outside the US have acted swiftly to enjoin such activities. For example, on February 24, 2017, a Danish court issued an injunction prohibiting Rebotix-Panama from, among other things, "marketing and offering the service . . . , in the course of which the Defendant resets the use counter of *EndoWrist* Instruments' memory chip and installs the Defendant's *Interceptor Board*, with a view to sale in Denmark." See Attachment B (English translation). On June 29, 2017, a German court issued a preliminary injunction placing similar restrictions on Rebotix- Panama.[2] See Attachment C (English translation).

[2] Intuitive is currently in litigation against Restore in the United States, in which Intuitive has asserted a number claims against Restore regarding its remanufacturing of EndoWrist instruments. With respect to the applicability of the 510(k) requirement to Restore's activities, the United States District Court for the Northern District of Florida stated the following in a November 2019 Order on Motion to Dismiss: "The FDA may decide that this statement [that a 510(k) clearance is not required for Restore's remanufacturing activities] is false, but the Court will not do so because it agrees with Plaintiffs that determining the truth or falsity of the statement would require it to 'make determinations . . . more properly within the exclusive purview of the FDA . . . .'" See Restore Robotics, LLC v. Intuitive Surgical, Inc., No. 5:19-cv-00098-TKW-MJF, Order on Motion to Dismiss at 6 (N.D. Fla. Nov. 14, 2019).

For all of the reasons set forth above, Intuitive respectfully requests that FDA promptly investigate the EndoWrist Remanufacturers' activities and take any appropriate actions. We would be happy to provide FDA with information necessary to assist the Agency in its investigation of the EndoWrist Remanufacturers. We will be in touch shortly to arrange a mutually convenient time for a meeting to discuss these issues.

Sincerely,

Dr. Myriam Curet
Executive Vice President and Chief Medical Officer

CC:
Dr. Binita Ashar, Center for Devices and Radiological Health, Food and Drug Administration
Mr. Bryan Benesch, Center for Devices and Radiological Health, Food and Drug Administration

Attachment A

Restore Robotics
Replace. Repair. Restore.

# Discussion of Risk Management and Liability With Regard to Surgical Robot Instrument Repair

## Risk Management

Restore Robotics understood that any interaction with the robot would receive extra scrutiny so we achieved ISO 9001 certification for our repair facility and designed, built and consistently execute the repair process in a manner that has been validated to the highest international standards. These include the following:

1. Repair process flow created according to ISO:13485:2012
2. Repair processes validated according to ISO:13485:2012
3. Compliance with Risk Management and Analysis according to EN ISO 14971:2012 (meets ISO and FDA standards)
4. Compliance to Biocompatibility ISO 10993 Biological Evaluation of Medical Devices
5. Compliance to Medical Electrical Equipment standards IEC 60601
6. Verification reports to Simulated Life Testing according to ISO:13485:2012
7. Software validation according to ISO:13485:2012

Restore Robotics is unaware of any other repair facility that has performed such expensive and comprehensive testing of a repair process.

Furthermore, our service violates none of the standards that could necessitate a 510K. That is to say

- The hospital never loses ownership of the instrument
- We do not sterilize nor do we provide a sterile device after the repair
- There are no changes to the performance or safety specifications of the instrument.
- The devices intended use is not significantly altered
    - The EndoWrist's 510K and IFU denote the instrument as a reusable device and they remain so
    - By the FDA's definition, in order to violate the standard of "significantly altered" we would have to change the EndoWrist into a single use device.

Restore Robotics has more than 2 years of history with repairing EndoWrist instruments with well over 1500 repairs resulting in No adverse events and No communication issues between the repaired instrument and the Da Vinci system.

## Liability

Other than the manner in which they are driven (human hand vs mechanics) these devices operate like any other endoscopic instrument hospitals have used for decades, thus Restore Robotics liability would be the same as any other 3rd party company a hospital currently utilizes to perform endoscopic instrument repairs.



Corp. Ofc. - 1275 Buford Hwy Ste 109 Suwanee Ga 30024
Repair Center - 4883 E. La Palma Ave, Suite 501B, Anaheim, CA 92807
WWW.RestoreRobotics.Com 678-619-0011

Restore Robotics
Replace. Repair. Restore.

Attachment B

**Excerpt of order - page 1 and pages 19-22**

Glostrup Court

# Order

made on 24 February 2017 in case No. BS 100-360/2017:

Intuitive Surgical Inc.
1020 Kifer Road Sunnyvale
CA 94086-5304 USA
[Claimant]

versus

Rebotix-Panama
Plaza Commercial Coronado #5 Playa
Coronado
Republic of Panama
[Defendant]

**Background and the parties' claims**

Under these injunction proceedings, which were brought before Glostrup Court on 8 February 2017, the Claimant, Intuitive Surgical Inc. has raised the following claims:

1. That the Defendant be restrained from marketing and offering the service *Rebotix EndoWrist Servicing Process* as described in Exhibit 7, in the course of which the Defendant resets the use counter of *EndoWrist Instruments*' memory chip and installs the Defendant's *Interceptor Board*, with a view to sale in Denmark.

2. That the Defendant be restrained from forwarding emails and letters or in any other way transmitting communications to hospitals in Denmark with identical or other unlawful content similar to the content of the email produced as Exhibit 7, whereby the Defendant markets its *Rebotix EndoWrist Servicing Process*.

3. That the Defendant be ordered to disclose names and addresses of recipients in Denmark of the email produced as Exhibit 7.

With respect to claims 1-3, the main request is for the restraining and mandatory

injunctions to be applicable in Denmark without advance notice to the Defendant, see section 417(3), 2nd sentence, of the Danish Administration of Justice Act, and alternatively for them to be applicable in Denmark after prior notice to the Defendant, see 417(3), first sentence, of the Danish Administration of Justice Act.

In view of the nature of the case and the fact that the Defendant is domiciled in Panama, the Court had no objection to conducting a hearing in the case on 17 February 2017 without prior notice to the Defendant, see section 417(3) of the Danish Administration of Justice Act. The case has thus been decided without giving the Defendant a chance to make a statement.

The Order does not include a complete statement of claim, see section 218b of the Danish Administration of Justice Act.

**Pages 19-22**

**The Court's decision and grounds**

The Court has regard to the fact that the Defendant's service, *Rebotix EndoWrist Servicing Process*, targets the Claimant's medical device, Endowrist Instruments, and in particular EndoWrist Needle Drivers and EndoWrist Graspers.

The Court also has regard to the fact that EndoWrist Needle Drivers and EndoWrist Graspers contain an electronically programmable system in the form of a memory chip.

According to the Danish Act on Medical Devices incorporating Council Directive 93/42 of 14 June 1993 on medical devices and subsequent directives, and Order No. 1263 of 15 December 2008 issued in pursuance of the Act, medical devices may only be marketed, traded, distributed and used on condition that the specific requirements and procedures set out in the Order have been fulfilled and followed.

Medical devices must be subjected to a so-called conformity assessment procedure according to which exact procedures must be followed, depending on the risk associated with the use of the device. Medical devices that comply with Community requirements for safety, quality and performance are furnished with a CE mark.

It is evident from the Claimant's EC certificate, which was issued on 14 December 2016 by Presafe Denmark A/S, the notified body for certification and control procedures in respect of medical devices in Denmark, that Needle Drivers and Graspers classified as medical devices in risk class II, comply with the requirements of section 6(3) of the Order on full quality assurance.

It is evident from the EC certificate, inter alia, that the Claimant must not make any fundamental changes with regard to the quality system without the prior

approval of Presafe Denmark A/S.

It is evident from a print-out of a technical file, which according to our information was included in the conformity assessment procedure performed by Presafe Denmark A/S, that EndoWrist Needle Drivers and Graspers are programmed for a predetermined number of uses to help ensure the reliable and consistent performance of the instruments.

The Court has regard to the fact that the Claimant's EndoWrist Instruments, which are covered by the CE mark[1], including the EndoWrist Needle Drivers and Graspers, comply with the statutory requirements that medical devices must fulfil in order for the products to be marketed, traded, distributed and used in Denmark.

On the basis of the information at hand, the Court has regard to the fact that the Interceptor Board that the Defendant applies to reset the [use counter] of the memory chip in the EndoWrist Instruments fails to comply with the statutory requirement that medical devices must be subjected to a conformity assessment procedure as described above.

The Claimant warrants the reliable and consistent performance of the medical device, EndoWrist Instruments, and any changes in quality assurance brought about through the manipulation of the predetermined ten uses of EndoWrist Instruments for surgical procedures are found to be contrary to good marketing practice under the present circumstances. The Court is therefore satisfied that by offering the service *Rebotix EndoWrist Servicing Process* for sale on the Danish market, the Defendant has acted unlawfully vis-a-vis the Claimant and has contravened section 1 of the Danish Marketing Practices Act.

The Defendant's email of 6 December 2016 from the Defendant to nurse Louise Birch Møller, Herlev Hospital, in which the Defendant offers the service *Rebotix EndoWrist Servicing Process* is thus in contravention of section 1 of the Danish Marketing Practices Act on good marketing practice. It should be noted that the Court is also satisfied that the disparagement of the Claimant that is evident from the email is in itself contravention of section 1 of the Danish Marketing Practices Act.

It is evident from the email of 6 December 2016 from the Defendant to nurse Louise Birch Møller, Herlev Hospital, that the Defendant, in its marketing of *Rebotix EndoWrist Servicing Process*, makes a number of statements about its service and disparages the medical devices of the Claimant. The court finds that it has been rendered probable that several of the statements made, as indicated by the Claimant, are misleading, incorrect and deceptive and are likely to distort the economic choices made in the hospital sector and unduly influence potential clients in the hospital sector. Accordingly, the Court finds that it has been rendered

[1] Translator's footnote: the text reads "EC mark"

probable that section 3(1) and (2) of the Danish Marketing Practices Act has been contravened.

Furthermore, the Court finds that it has been rendered probable that the content of the email of 6 December 2016 implies an infringement of section 5(2) of the Danish Marketing Practices Act. The Court has regard to the fact that it has been rendered probable that the comparative advertising used in the email is misleading and disloyal towards the Claimant.

The Court has regard to the fact that the Claimant holds EU trademark registrations for the word marks "DA VINCI" and "ENDOWRIST", and that "ENDOWRIST" is registered in classes 10, 41 and 42; in other words, in the class (class 10) covering medical devices, surgical instruments, components for surgical manipulator systems and medical devices for use in connection with surgical manipulator systems for surgical procedures.

The Court finds that the information on the case renders it probable that, by using the Claimant's trademark "ENDOWRIST" in the name of the Defendant's service "Rebotix Endowrist Servicing Process", and considering the similarity in the type of goods, the Defendant infringes the Claimant's trademark right, see section 4(1) of the Danish Trade Marks Act.

At the same time, the Court finds that it has been rendered probable that the use of ENDOWRIST in the context mentioned implies an infringement of the Claimant's rights pursuant to section 18 of the Danish Marketing Practices Act.

In conclusion, the Court is satisfied that the Defendant has contravened section 1 of the Danish Marketing Practices Act in that it has marketed and offered the service *Rebotix Endo Wrist Servicing Process* for sale, and in this connection the Court is satisfied that the Claimant has the right that it seeks to protect under claims 1 and 2 for restraining injunctions and claim 3 for a mandatory injunction. Furthermore, the Court finds that it has been rendered probable that the Defendant has contravened section 3(1) and (2), section 5(2) and section 18 of the Danish Marketing Practices Act as well as section 4(1) of the Danish Trade Marks Act, and that the Claimant[2] has rendered probable the right for which protection is sought.

According to the information at hand concerning the Defendant's marketing, for instance the communication with Herlev Hospital, the Court finds it necessary, in view of Defendant's conduct, to grant the restraining and mandatory injunctions claimed.

With due regard to the nature and circumstances of the case, including the detrimental effects that the Defendant's marketing may have on the Claimant, together with the fact that the Defendant offers its services via email and a website

[2] Translator's footnote: the text reads "Defendant"

in Panama, the Court finds that the Claimant would forfeit its possibility of successfully protecting its rights if the Claimant were to wait for the dispute to be settled in court.

Accordingly, and since none of the circumstances set out in section 414 of the Danish Administration of Justice Act are deemed to exist, the conditions for granting the restraining and mandatory injunctions claimed are fulfilled.

In view of the nature of the case, the provision of security is not necessary.

The Court directed that the Defendant pay DKK 20,300 in legal costs to the Claimant. Legal costs are made up of DKK 300 in court fees and a suitable amount to cover the assistance of counsel of DKK 20,000.

In fixing the legal costs the Court has had regard to the nature of the case and its outcome.

**It is held that:**

The Defendant, Rebotix-Panama, is to be restrained from marketing and offering the service *Rebotix EndoWrist Servicing Process* for sale as described in Exhibit 7, in the course of which the Defendant resets the use counter of *EndoWrist Instruments*' memory chip and installs the Defendant's *Interceptor Board*, with a view to sale in Denmark.

The Defendant, Rebotix-Panama, is to be restrained from forwarding emails and letters or in any other way transmitting communications to hospitals in Denmark with identical or other unlawful content similar to the content of the email produced as Exhibit 7, whereby the Defendant markets the service *Rebotix EndoWrist Servicing Process*.

The Defendant, Rebotix-Panama, ~~is to be restrained from~~* disclosing names and addresses of recipients in Denmark of the email produced as Exhibit 7.

The Defendant is to pay to the Claimant the costs of the case amounting to DKK 20,300 within 14 days.

The legal costs determined carry interest in accordance with section 8a of the Danish Interest Act.

Justice Janne Rostrup Hansen

* Correction in pursuance of section 221(1) of the Danish Administration of Justice Act so that "restrained from" is deleted and replaced by "ordered to".

Glostrup Court, 27 February 2017.

Justice Janne Rostrup Hansen

Attachment C

**Regional Court of Hamburg**
**Ref.: 315 O 273/16**

**Decision**

In the matter

**Intuitive Surgical, Inc.,**
represented by its CEO, Mr. Cary S. Guthart,
1020 Kifer Road, Sunnyvale, CA 94086-5304, United States

**- Applicant -**

Attorney of record:
Lawyers Hogan Lovells International LLP,
Alstertor 21, 20095 Hamburg, Ref.: 350 Has 1H6998.000020

versus

**Rebotix Panama S.A.,**
represented by its directors,
Plaza Commercial Coronado #5, Playa Coronado, Panama

**- Respondent -**

the Regional Court of Hamburg – Civil Chamber 15 – by the Presiding Judge at the Regional Court Dr. Enderlein, the Judge at the Regional Court Harder and the Judge at the Regional Court Dr. Kohls decides on 29 June 2017:

I. By way of a preliminary injunction – due to urgency, without a previous hearing – to avoid a fine to be set by the court for each case of infringement, and in the event that this cannot be collected, custody or imprisonment of up to 6 months (fine in the individual case to a maximum of € 250,000.00; custody for a maximum of 2 years), the applicant is

**prohibited**

from

offering and / or arranging for the offering and / or promoting and / or arranging for the promotion of a service in connection with *EndoWrist®* instruments, in which the original memory chip of the devices is placed on a so-called "interceptor board" and the use counter of the devices is reset, then the "Interceptor Board" is installed together with the original memory chip into the *EndoWrist®* instruments,

for business purposes

as described in **Exhibit ASt 5**

without having the necessary CE marking;

II. The respondent is ordered to pay the costs of the legal dispute based on an amount in dispute of EUR 100,000,--.

**Reasons**

The injunction claim is based on Art. 8, 3 para. 1, 3a a UWG [Law against unfair competition] in connection with Art. 6 and 7 of the MPG [Medical Devices Act]. The applicant has shown that the respondent is offering its service with regard to *EndoWrist®* instruments also in Germany. In this respect, it substantiated that the e-mail Exhibit ASt 8 has been addressed to a senior physician of a German hospital; the clinic has its own da Vinci surgical robot. The request / explanation of the respondent contains the sentence *„I pesume you have either a Davinci S or Si"* in this respect.

The applicant has also shown that the respondent has no CE certificate for its maintenance service promoted in Germany. This stems from the respondent's reply by its lawyer Löhde from 7 June 2017, in which he states that *"A CE mark is not required or appropriate for components"*. Hereby, it doesn't depend on the CE certificate for spare parts or other components, but on the "essential modifications" to the respondent's medical device by resetting the use counter and by re-placing the modified medical device on the market.

The urgency has been proven as well. The applicant only had reliable knowledge that the respondent does not have a CE certificate by the letter of the lawyer Löhde from 7 June 2017.

**Legal instructions:**

This decision can be appealed. There is no time limit for the appeal. [...]

Dr. Enderlein Dr. Kohls Harder